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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,367	06/02/2006	Luca Rampoldi	291385US0PCT	3683

22850 7590 11/27/2009

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EXAMINER	
SULLIVAN, DANIELLE D	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,367	RAMPOLDI ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending and currently under examination.

Response to Arguments

In view of the applicant initiated interview on 4/22/2009 the Examiner agreed that the rejections under 112, 1st paragraph and US 7056951 would be withdrawn. Furthermore, the rejection under Manikandan et al. has been withdrawn because the granulate fails to comprise polyethylene glycol. However, upon further consideration, a new ground(s) of rejection is made in view of Applicants amendment.

Withdrawn rejections

Applicant's amendments and arguments filed 8/24/2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a granulate comprising "gabapentin 80-98% by weight, polyethylene glycol 2-25% by weight, additives 0-20% by weight". The lowest

percentage gabapentin and the highest percentage of polyethylene glycol exceed 100% even with 0% additives. This is indefinite and the metes and bounds of the ranges cannot be deciphered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the claims to recite "a gabapentin granulate obtained by melt granulating gabapentin". The term "melt granulating" is not supported anywhere by the specification.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polyethylene glycol 1500, 4000 and 6000 does not reasonably provide enablement for polyethylene glycol having a melting point of 50 to 80 degrees Celsius. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claim 1 recites polyethylene glycol having a melting point of 50 to 80 degrees Celsius.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention
2) the state of the prior art
3) the relative skill of those in the art
4) the predictability of the art
5) the breadth of the claims
6) the amount of direction or guidance provided
7) the presence or absence of working examples
8) the quantity of experimentation necessary

The nature of the invention.

The claimed invention relates to a gabapentin granulate obtained from granulating gabapentin and polyethylene glycol having a melting point of 50 to 80 degrees Celsius.

The state of the prior art & predictability of the art

It is generally accepted that only polyethylene glycols 4000 and 6000 have melting points within this range.

The breadth of the claims

The claims are broad and direct to any polyethylene glycol having a melting point of 50 to 80 degrees Celsius.

The presence or absence of working examples

The specification provides detailed evaluation of granulates comprising polyethylene glycol 1500, 4000 and 6000. However, working examples only polyethylene glycols 4000 and 6000 have a melting point of 50 to 80 degrees Celsius.

Therefore, it would require undue experimentation to determine how to make the claimed composition commensurate to the scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 10-13 and 16-18 rejected under 35 U.S.C. 102(b) as being anticipated by Spireas (2002/0091159).

Spireas disclose solid dosage forms comprising gabapentin and polyethylene glycol prepared by granulation (Table 3-5). Examples 16 and 23 disclose formulations comprising 74% gabapentin, 1.8% polyethylene with remainder being additives. The formulations are capsules (column 3, lines 25-29; column 13, lines 7-19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 7-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spireas (2002/0091159)).

Applicant's Invention

Applicant claims a gabapentin granulate obtained by granulating gabapentin with polyethylene glycol having a melting point comprised between 50 and 80. Claims 5, 7-9 and 15 specify the granulate is in the form of a compressed tablet.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Spireas teaches pharmaceutical formulations comprising gabapentin and polyethylene glycol prepared by granulation (Table 3-5). Examples 16 and 23 disclose formulations comprising 74% gabapentin, 1.8% polyethylene with remainder being additives. The formulations are capsules (column 3, lines 25-29; column 13, lines 7-19). The formulations can be processed into a stable solid dosage form selected from tablets and gelatin capsules [0014] and [0040].

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Spireas does not exemplify tablets. However, the tablet forms are taught.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Spireas to formulate a tablet. One would have been motivated to formulate the granulate as a tablet because Spireas teaches the formulations may be solid tablet or capsules.

Claims 2-4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spireas (2002/0091159) in view of Reo et al. (US 5,429,825).

Applicant's Invention

Applicant claims a gabapentin granulate obtained by granulating gabapentin with polyethylene glycol having a melting point comprised between 50 and 80. Claims 2 and 3 specify the gabapentin is higher than 80 and 90% by weight of the total weight of the granulate. Claim 4 specify the gabapentin is 98% and the polyethylene glycol is 2% by weight based on the total weight of the granulate. Claim 14 specifies the granulate comprises 80-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Spireas teaches pharmaceutical formulations comprising gabapentin and polyethylene glycol prepared by granulation (Table 3-5). Examples 16 and 23 disclose formulations comprising 74% gabapentin, 1.8% polyethylene with remainder being additives. The formulations are capsules (column 3, lines 25-29; column 13, lines 7-19).

The formulations can be processed into a stable solid dosage form selected from tablets and gelatin capsules [0014] and [0040].

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Spireas does not teach gabapentin is higher than 80 and 90% by weight of the total granulate. Spireas does not specify the granulate comprises 80-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives, preferably 98% gabapentin and 2% polyethylene glycol. It is for this reason that Reo et al. is joined.

Reo et al. teach a method of rotomelt granulating at least one powdered pharmaceutically active material and a powdered excipient material (abstract). The process solves the problem of inactivation of water sensitive pharmaceuticals when a solvent based granulation process is used (column 1, lines 40-65). Excipients include polyethylene glycol 4000 and 6000 (column 4, lines 60-63). The active ranges from 10-80% and optionally contains the excipients in a range of 0-60% excipients, Wherein the total weight is 100 weight percent (column 5, lines 11-23). Reo et al. do not teach specific amounts preferably 98% gabapentin and 2% polyethylene glycol. However, in view of In re Aller, Lacey, and Hall, 105 USPQ 233 (C.C.P.A. 1955), "change in concentration is not patentable modification, however, such changes may impart patentability to process if ranges claimed produce new and unexpected results". Since Spireas disclose the invention as being used as a pharmaceutical formulation and only lack in specifying the amounts obtained the present claims are prima facie obvious.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Spireas and Reo et al. to further include adjusting the amount of gabapentin to higher than 80 and 90%, preferably 98% gabapentin and 2% polyethylene glycol. It is routine optimization for one of ordinary skill in the art to adjust ingredients in a composition to optimize the desired results of the composition. In this case the amount of gabapentin and to polyethylene glycol is routine optimization.

Response to Amendment/Declaration

The declaration under 37 CFR 1.132 filed 8/24/2009 is insufficient to overcome the rejections because: the data is not in the form of a true side-by-side comparison and the showing is not commensurate with the claims.

The data compares the spectra of the granulate produced by gabapentin co-melted with macrogol and gabapentin standard. The comparison should be against wet granulated with macrogel 4000. Furthermore, data is not thoroughly discussed to show exactly what is unexpected. The showing is hence, not commensurate is scope because one cannot correlate the showing to the recitation of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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